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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/069,285	08/08/2002	Roland Suck	MERCK 2386	8082

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MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
2200 CLARENDON BLVD.
SUITE 1400
ARLINGTON, VA 22201

EXAMINER

SZPERKA, MICHAEL EDWARD

ART UNIT	PAPER NUMBER
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1644

MAIL DATE	DELIVERY MODE
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05/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/069,285

Applicant(s)

SUCK ET AL.

Examiner

Michael Szperka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 9-21, 24 and 26-33 is/are rejected.
- 7) ☒ Claim(s) 22, 23 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicant's response and amendment received February 20, 2007 is acknowledged.

Claims 1-8 have been canceled.

Claims 9 and 24 have been amended.

Claims 29-33 have been added.

Claims 9-33 are pending and are under examination in the instant office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. The rejection of claims 9-28 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention has been withdrawn in view of applicant's claim amendments received February 20, 2007.
Specifically, applicant has deleted the recitation of "soluble constituents" from the independent claims, thus rendering the rejection of record moot.
4. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
5. Claims 9-21, 24, and 26-28 stand rejected and new claims 29-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the

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specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention for the reasons of record.

The office action mailed 11/17/2006 states:

Applicant has claimed a broad method by which specific allergens from any and all Gramineae (grass) pollens can be purified. The allergens that can be purified by the recited method include groups 1, 2, 3, 10, and 13. The specification includes a working example wherein said allergens were purified from an aqueous extract of *Phleum pretense*, also known as timothy grass. Dependent claim 10 recites seven specific grasses from which said allergens are to be obtained, one of which is timothy grass.

The taxonomic family of Gramineae comprises more than 600 genera and 10,000 species (Esch, R.E. in Allergens and Allergen Immunotherapy, 3rd edition, pages 185-205, see particularly the top of page 186). The specification discloses where in the prior art information concerning the structure and characterization of group 1, 2, 3, and 10 allergens can be found (see particularly the paragraph spanning pages 1 and 2). It is known in the art that some allergens, such as group 5, are only found in a subset of the members of Gramineae, while other allergens such as group 6 appear to only be found in timothy grass (Esch, pages 194-196). Disclosure of group 13 grass allergens in the art does not appear to have occurred prior to the filing of applicant's instant invention. In the instant application, applicant identified material in a particular fraction as being the group 13 allergen from timothy grass, but structural information such as the amino acid sequence of the allergen, or identification of its function in the plant is not disclosed. Note that the determination of if a polypeptide is or is not an allergen is not based upon intrinsic properties of the polypeptide but is instead a context-specific determination since it is known that allergenicity of a polypeptide cannot be determined *a priori* on a structural basis, presumably because the induction of an allergic response is a complicated process involving the interplay of diverse genetic and environmental factors that are not fully understood (Bumenthal et al., in Allergens and Allergen Immunotherapy, pages 37-50, see entire document, particularly the last sentence of the third full paragraph of page 39 and Figures 1 and 2).

The guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant

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was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Fri. January 5, 2001, see especially page 1106 column 3).

In The Regents of the University of California v. Eli Lilly (43 USPQ2d 1398-1412) 19 F. 3d 1559, the court held that disclosure of a single member of a genus (rat insulin) did not provide adequate written support for the claimed genus (all mammalian insulins) and also stated:

"A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin [e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material."

The court has further stated that "Adequate written description requires a precise definition, such as by structure, formula, chemical name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." Id. at 1566, 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). Also see Enzo-Biochem v. Gen-Probe 01-1230 (CAFC 2002).

As discussed above, the instant application appears to be the first time that group 13 allergens are disclosed, and it is known that many previously identified grass pollen allergens are not present in all Gramineae pollens. As shown in table 1 of Esch, the grass species recited in claim 10 do not appear to be a representative sampling of Gramineae since all of the recited species are found within the subfamily Pooideae. Further, the working example demonstrates that the group 13 allergen can be isolated from timothy grass, but no examples are provided for the other positively recited grass species, and applicant has not disclose the structure of the group 13 allergen that mediates its property of being an allergen in a subset of humans afflicted with grass pollen allergies.

Therefore, it appears that the broad purification method claimed by applicant lacks adequate written description because there does not appear to be any correlation between structure of a group 13 allergen and its role in human allergy. The method also appears to lack adequate written description because the instant disclosure does not provide a representative number of examples of grass pollens that comprise the group 13 allergen since knowledge of this allergen was not known in the prior art and applicant has isolated it only from a single grass species, timothy grass. As such a skilled artisan would reasonably conclude that applicant was not in possession of the claimed purification method

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that is applicable to the 10,000+ members of the genus of Gramineae pollen at the time the application was filed.

Applicant's arguments filed February 20, 2007 have been fully considered but they are not persuasive. Applicant argues that the designation Phl p 13 was assigned to the polypeptide isolated by the claimed method by WHO-IUIS, not the inventors of the instant application, and that "others in the art were in possession of these data and information (concerning Phl p 13) or could have access to it at the filing date, and also even at the priority date of the present application". To support this argument, applicant provides references by Suck et al., Petersen et al., and discusses US application 09/959,340 (PCT/EP00/03259, published as WO 00/65060 on November 2, 2000).

This argument is not persuasive because all of these references were not published until after the priority date of the instant invention and are not applicable as prior art under any section of 35 USC 102. Therefore it is not clear how other skilled artisans could be in possession of information concerning Phl p 13 prior to the priority date of the instant invention. Further, as applicant points out in their response, the teachings of the references argued by applicant pertain only to timothy grass, i.e. *Phleum pratense*.

Applicant argues that even though the teachings discussed above, and the example of the instant specification, are limited only to *Phleum pratense* this is not sufficient reason for rejection since the allergen art is not unpredictable because "One of ordinary skill in the art can perform trial runs using different grasses by performing the claimed purification process, even if the end result, e.g., whether a group 13 allergen will be purified, may have some uncertainty associated with it" is reasonable in this particular art, citing *In re Angstadt* for precedent.

This argument is not persuasive because such an argument pertains to making and using the claimed invention. The instant invention has not been rejected for lacking enablement on how to make and use, but rather stands rejected under written description.

Applicant acknowledges that *In re Angstadt* dealt with issues of making and using rather than written description, but argues that other court decisions such as

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Capon v. Eshhar and *Falkner v. Inglis* indicate that broad generic claims have written description even when examples are limited to only a single species. Applicant argues that such generic claims have support when a skilled artisan would be reasonably expected to know or readily identify what is being claimed. "Thus, the requirement that applicants provide structural information, etc., for the group 13 allergens is not warranted in the present case where it is demonstrated that prior art can provide such information to those of ordinary skill in the art." Applicant then argues how the Petersen reference discloses that group 13 allergens occur in other plant species.

This argument is not persuasive because as is discussed above, the characteristics of Group 13 allergens are not known in the prior art. As such, while the specification need not provide a written description of things which are readily known to skilled artisans, the lack of a prior art date for any of the references provided by applicant to indicate public knowledge of group 13 allergens prior to the priority date of the instant application indicates that group 13 allergens were not readily known to skilled artisans at that time.

Applicant also argues that information concerning the inability to detect, for example, group 5 and group 6 allergens in some plants has no bearing on what would be expected for group 13 allergens.

While group 13 allergens are structurally distinct from group 5 and 6 allergens, it illustrates the fact that not all allergens are found in all plants and as such a skilled artisan would know that isolation of an allergen from one plant does not guarantee that the same allergen can be isolated from some other plant.

The rejection is maintained.

Claim Objections

6. The objection to claims 9 and 24 has been removed in view of applicant's claim amendments received 2/20/07 to recite Gramineae.

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7. Claims 22, 23, and 25 are objected to as being dependent upon a rejected independent claim, but would be allowable if rewritten in independent form including all of the limitations of the independent claim and any intervening claims.

8. No claims are allowable.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael Szperka, Ph.D.
Patent Examiner
Technology Center 1600
April 19, 2007



4/13/07
G.R. EWOLDT, PH.D.
PRIMARY EXAMINER